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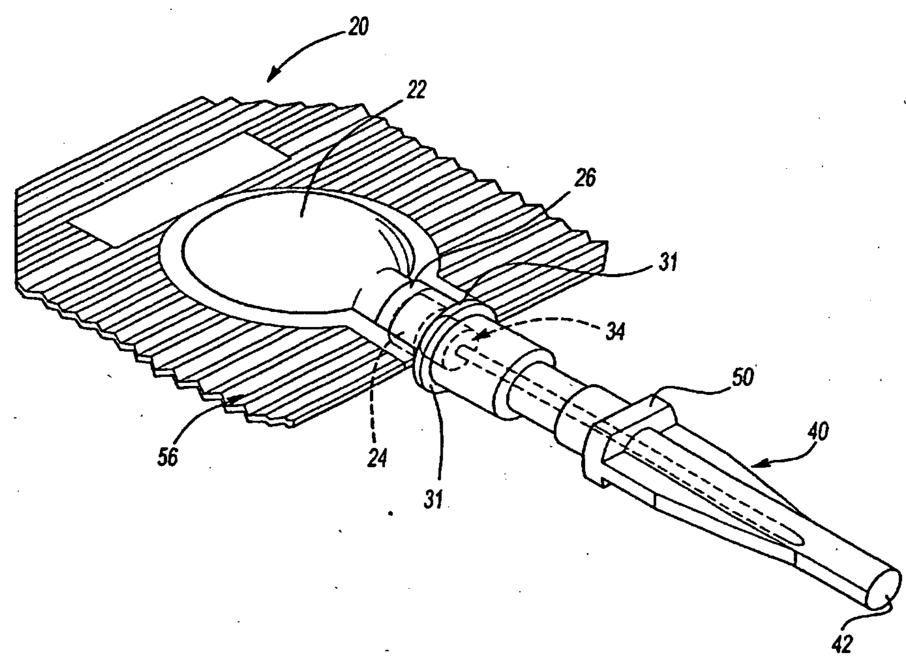
(54) Title: SINGLE-USE DISPOSABLE SYRINGE



(57) **Abstract:** A medical fluid delivery device having a collapsible crushable enclosure wall formed of a laminate including an inner film layer of low density polyethylene bonded to an outer layer of cyclic olefin or cyclic olefin copolymer having a melting temperature of 1 to 10 °C greater than the melting temperature of the inner film layer. The outer film layer may be a blend of cyclic olefins or cyclic olefin copolymers and the inner film layer may comprise a first inner layer of linear low density polyethylene and an intermediate layer of high pressure low density polyethylene.

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

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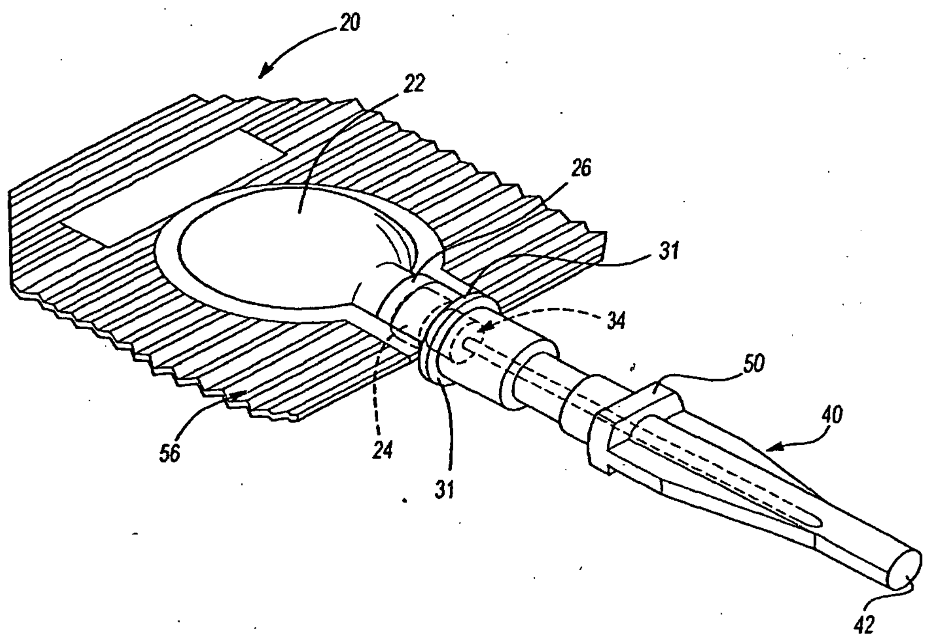
(54) Title: MEDICAL FLUID DELIVERY DEVICE



(57) **Abstract:** A medical fluid delivery device having a collapsible crushable enclosure wall formed of a laminate including an inner film layer of low density polyethylene bonded to an outer layer of cyclic olefin or cyclic olefin copolymer having a melting temperature of 1 to 10 °C greater than the melting temperature of the inner film layer. The outer film layer may be a blend of cyclic olefins or cyclic olefin copolymers and the inner film layer may comprise a first inner layer of linear low density polyethylene and an intermediate layer of high pressure low density polyethylene.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MEDICAL FLUID DELIVERY DEVICE

FIELD OF THE INVENTION

This invention relates to a medical fluid delivery device having a collapsible crushable enclosure wall containing the medical fluid or more particularly a single-use disposable delivery device, such as a syringe having a bulb-shaped compressible enclosure, formed of a laminate having an inner moisture barrier.

BACKGROUND OF THE INVENTION

Single-use medical fluid delivery devices having a collapsible wall enclosure which delivers the medical fluid to a patient upon compression of the enclosure wall are known in the art. As used herein, the terms "medical fluid" and "medical liquid" are intended to include medicaments, vaccines, drugs and the like which may be delivered to a patient by the delivery device. Generally, single-use disposable devices of this type include a bulb-shaped enclosure which contains the medical fluid or liquid. Thus, upon compression of the collapsible enclosure wall, the medical fluid or liquid is expelled from the enclosure through an outlet to the patient. Such single-use delivery devices may also be utilized in conjunction with a syringe, for example, wherein a medical liquid is delivered to a needle cannula for injection to a patient upon compression of the collapsible enclosure wall by the patient or a medical worker. That is, during injection, the patient or medical worker compresses the collapsible enclosure wall which delivers a medical liquid through the needle cannula to the patient.

U.S. Patent No. 4,955,871 discloses a single-use disposable syringe which includes a reservoir for a medical liquid formed from two sheets of thermoplastic sealed together in face-to-face relation, wherein a bulb-shaped central portion is formed by either injecting air under pressure between the sheets into a die cavity or vacuum forming. The disclosed single-use disposable syringe further includes a double ended needle cannula supported on a hub which is received within a tubular nozzle portion of the blow molded or vacuum formed delivery device to pierce a membrane within the tubular nozzle portion and provide fluid communication between the liquid reservoir in the bulb-shaped delivery device and the needle cannula. Prior to use, the patient or

healthcare worker drives the sharp end of the needle cannula through the membrane to establish fluid communication between the reservoir and the needle cannula. Then, during injection, the user compresses the bulb-shaped delivery device, thereby delivering the medical liquid through the needle cannula to the patient. A cap having a radial rib is provided to protect against accidental needle sticks and to assist in driving the needle cannula through the membrane. The single-use disposable syringe disclosed in this patent is not reusable because the bulb-shaped reservoir is substantially collapsed during use to expel medicament out of the reservoir, such that the bulb-shaped reservoir cannot be reformed.

As set forth below, the medical fluid delivery device of this invention is directed to the material selected for the delivery device, which in U.S. Patent No. 4,955,871, is the bulb-shaped reservoir formed by bonding and blow or vacuum forming the sheets as described above. The thermoformable sheets disclosed in U.S. Patent No. 4,955,871 are a laminate comprised of an outer film of polyethylene terephthalate, a bonding layer formed from an emulsion of polyvinylidene chloride, which is coated on the polyethylene terephthalate film and dried, and an inner layer of polyethylene film which is glued to the polyethylene terephthalate film using polyurethane as the adhesive. The delivery device is then formed by bringing two laminated sheets together described above, heating the sheets to their thermoforming temperature and then either blow molding or vacuum forming the sheets in a die, forming the bulb-shaped delivery device and an integral tubular nozzle described above. The laminate selected for the single-use disposable syringe disclosed in U.S. Patent No. 4,955,871 has several disadvantages as follows. First, following radiation sterilization, extractables are found in the medical liquid at least in trace amounts. Second, the bonded sheets are subject to delamination. Third, during incineration of the delivery device following use, the polyvinylidene chloride creates hydrochloric acid and the polyurethane produces further toxins. Finally, the manufacturing process is expensive, requiring either special equipment or manual operations. Therefore, there is a need to provide a safe disposable medical liquid delivery device which avoids the problems described.

SUMMARY OF THE INVENTION

The medical fluid delivery device of this invention has a collapsible crushable enclosure wall formed of a thermoformable laminate and is therefore suitable for many applications, including but not limited to the single-use disposable syringe disclosed in the above-referenced U.S. Patent No. 4,955,871, the disclosure of which is incorporated herein by reference. As will be understood, however, the medical fluid delivery device of this invention is not limited to the disposable syringe disclosed in this patent, but may be utilized with any medical fluid delivery device having a collapsible crushable enclosure wall, particularly including liquid fluid delivery devices subject to radiation sterilization and which may be formed by conventional thermoforming methods.

The collapsible crushable enclosure wall of the medical fluid delivery device of this invention preferably includes an inner layer film of low density polyethylene forming a moisture barrier as described in the above-referenced U.S. Patent. However, the outer layer film is formed of a cyclic olefin or a cyclic olefin copolymer preferably having a melting temperature of between 1 to 10° C greater than the melting temperature of the inner layer of film of low density polyethylene and bonded directly to the inner layer film of low density polyethylene. In a preferred embodiment, the inner layer film of low density polyethylene and the outer layer film of cyclic olefin or cyclic olefin copolymer are coextruded and bonded together in face-to-face relation during the coextrusion process. Alternatively, the low density polyethylene film can be bonded to the cyclic olefin or cyclic olefin copolymer during extrusion of the low density polyethylene film, although not preferred. The preferred process prevents delamination and results in a superior delivery device. The films may then be bonded together and thermoformed by conventional methods as described, for example, in the above-referenced U.S. Patent. After filling the reservoir formed between the films with a medical fluid, the delivery device may be sterilized by radiation without extractables in the medical fluid or liquid in the reservoir. Further, the delivery device is transparent, having improved clarity over the prior art including the above-referenced U.S. Patent.

Although the thickness of the laminate and the lamina forming the laminate will depend to some extent upon the application, the outer layer film of cyclic olefin or

cyclic olefin copolymer has a thickness of between 1 and 7 mils, preferably 3 to 6 mils and most preferably about 5 mils. The inner layer film of low density polyethylene preferably has a thickness of between 1 and 4 mils or preferably about 3 mils, particularly where the inner layer of low density polyethylene is formed of a laminate as now described. In a preferred embodiment, the first layer film in contact with the medical fluid is formed of a linear low density polyethylene, providing improved strength at ambient temperatures during filling, storage and use, and the second layer between the first layer and the outer layer of cyclic olefin or cyclic olefin copolymer is formed of a film of high pressure low density polyethylene providing strength at elevated temperatures during forming. That is, the crushable enclosure wall is formed of a laminate comprising at least three film layers including a first inner film layer formed of linear low density polyethylene, a second inner film layer formed of high pressure low density polyethylene and an outer film layer formed of a cyclic olefin or cyclic olefin copolymer, wherein the outer film layer has a melting temperature of between 1 and 10° C greater than the melting temperature of the inner film layers, preferably both the first and second inner film layers, to assure uniform heat softening of all three film layers during thermoforming. In a preferred embodiment, all three film layers are coextruded and bonded together during coextrusion, wherein the first inner film layer of linear low density polyethylene has a thickness of between 1 and 3 mils, preferably about two mils and the second inner film layer of high pressure low density polyethylene has a thickness of between 0.5 and 2 mils, preferably about 1 mil.

As set forth above, the outer film layer formed of a cyclic olefin or cyclic olefin copolymer preferably has a melting temperature of 1 to 10° C greater than the inner layer film or films of low density polyethylene or more preferably between 3 and 7° C or about 4 to 5° C. Thus, in a preferred embodiment, the outer film layer is formed of a blend of cyclic olefins or cyclic olefin copolymers to achieve the desired properties, including melting temperature. The medical fluid delivery device of this invention thus achieves the objects of this invention including improved formability, reduced manufacturing cost as compared to the laminate described in the above-referenced U.S. Patent, reduction or elimination of delamination of the laminate, improved clarity, reduction or elimination of extractables in the medical fluid and safe disposal, including incineration.

Further advantages and meritorious features of the medical fluid delivery device of this invention will be more fully understood from the following description of the preferred embodiments, the claims and the appended drawings, a brief description of which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded view of a single-use disposable syringe which includes the medical fluid delivery device of this invention;

Figure 2 is an assembled view of the single-use disposable syringe shown in Figure 1;

Figure 3 illustrates the single-use disposable syringe of Figures 1 and 2 during injection after collapse of the delivery device;

Figure 4 is a cross-sectional view of the delivery device shown in Figure 1 in the direction of view arrows 4-4; and

Figure 5 is a cross-sectional view similar to Figure 4 illustrating a second preferred embodiment of the drug delivery device of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As set forth above, the medical fluid delivery device of this invention having a collapsible crushable enclosure wall reservoir may contain any fluid medicament, drug or vaccine and is particularly useful for liquid medicaments, drugs and vaccines, referred to herein as medical fluids or medical liquids, and is therefore not limited to any specific delivery device. However, the delivery device of this invention will now be described in the context of the single-use disposable syringe described in the above-referenced U.S. Patent No. 4,955,871 for ease of description only and without limitation of the embodiment of the delivery device except as specifically set forth hereinbelow.

First, referring to Figures 1 to 3, a medical liquid delivery device 20 is disclosed in combination with a disposable syringe as disclosed in the above-referenced U.S. Patent. The delivery device 20 includes a bulb-shaped reservoir 22 having a tubular outlet or nozzle portion 24 in fluid communication with the bulb-shaped reservoir 22 including a pierceable membrane 26 and an outlet 28. The tubular outlet portion 24

includes an internal annular rib 30 spaced from the pierceable membrane 26 and an external annular rib 31. As described, the delivery device 20 may be formed by conventional thermoforming techniques.

The syringe assembly includes a double ended needle cannula 32, which is secured by conventional means to a needle hub 34, wherein the double ended needle cannula 32 includes a first sharp end 36, which is received within the outlet 28 of the tubular outlet portion 24, and an opposed second sharp end 38 used for aspiration or injection. The second sharp end 38 is received in a cap 20 having a closed end 42 and an open end 44 which receives the second sharp end 38 of the needle cannula 32. The needle hub 34 includes a smaller diameter portion 46 having an external diameter for receipt in the open end 44 of the cap 40 and a larger diameter portion 48, having an external diameter for receipt in the outlet 28 of the tubular outlet portion 24. The cap 44 further includes an external rib 50 to assist in manipulation of the cap during use as now briefly described. As more fully described in the above-referenced U.S. Patent, the bulb-shaped reservoir is filled with a single dose of a medical liquid prior to use. The reservoir 22 is sealed by the pierceable membrane 26. The reservoir 22 may be filled with a filler tube (not shown) in fluid communication with the reservoir and then sealed. During use of the syringe, the first end 36 of the double ended needle cannula is received in the outlet 28 of the tubular outlet portion 24 of the delivery device 20 and then driven through the pierceable membrane 26 providing fluid communication between the bulb-shaped reservoir 22 and the double ended needle cannula 32. This may be accomplished by grasping the external rib 50 of the cap 40, wherein the open end 44 is received against the larger diameter portion 48 of the needle hub 34 and pushed by the user into the tubular outlet portion 24. The cap 40 is then removed as shown in Figure 3 exposing the second sharp end 38 of the double ended needle cannula 32 and the syringe is then ready for use. The user then compresses and collapses the bulb-shaped reservoir 22 during injection, which drives the medical liquid in the bulb-shaped reservoir 22 through the second sharp end 38 of the double ended needle cannula 32. As thus far described in this description of the preferred embodiments, the delivery device of this invention may be conventional and is not limited to the embodiment shown in Figures 1 to 3.

Figure 4 is a crosssection of one preferred embodiment of the medical liquid delivery device 20 of this invention, wherein the bulb-shaped reservoir 22 is a laminate comprised of an inner layer film 52 of low density polyethylene and an outer layer film 54 of a cyclic olefin or cyclic olefin copolymer. As described hereinbelow, the inner layer film 52 and the outer layer film 54 are preferably coextruded and then thermoformed, wherein the melting temperature of the outer layer film 54 has a melting temperature of between 1 and 10° C greater than the melting temperature of the inner layer film 52 or more preferably at least 4° C greater than the melting temperature of the inner film layer 52 as described above. One preferred method of forming the bulb-shaped reservoir 22 is to coextrude the inner layer film 52 with the outer layer film 54 as sheets or films, wherein the films 52 and 54 are brought together during the coextrusion process, intimately bonding the inner layer 52 to the outer layer 54. Then, during the thermoforming process, the film laminates are again heated to their melting temperature and thermoformed in a die (not shown), forming a peripheral portion 56 as described, for example, in the above-referenced patent. As described further below, in one preferred embodiment, the outer layer film 54 is a blend of cyclic olefins or cyclic olefin copolymers having a thickness of between 1 and 7 mils, more preferably between 3 and 6 mils, or preferably about 5 mils. The inner layer film has a thickness of 2 to 5 mils, preferably 2 to 4 mils, or more preferably about 3 mils.

Figure 5 illustrates a more preferred embodiment of the medical liquid delivery device 20, wherein the inner film layer is comprised of a first inner film layer 58 of linear low density polyethylene and a second inner film layer 60 of high pressure low density polyethylene. As described, the first inner film layer 58 of linear low density polyethylene provides improved strength at ambient temperature during filling, storage and use, and the second inner layer 60 of high pressure low density polyethylene provides improved strength during thermoforming, wherein the laminate is heated to its melting temperature. In one preferred embodiment, the first inner film layer 58 has a thickness of between 1 to 3 mils or about 2 mils and the second inner film layer 60 has a thickness of between 0.5 and 2 mils or about 1 mil.

As set forth above, a preferred embodiment of the medical fluid delivery device 20 of this invention includes an outer layer film 54 having a melting temperature slightly greater than the melting temperature of the inner film layer 52 as shown in

Figure 4 or film layers 58 and 60 shown in Figure 5, such that during thermoforming, the laminate is uniformly heated to its melting temperature. Thus, based upon the known commercially available cyclic olefins and cyclic olefin copolymers, the outer film layer 54 is preferably a blend of cyclic olefins or cyclic olefin copolymers to achieve the desired melting temperature.

Thus, for example, the outer film layer 54 may, for example, be a blend of Topas® 6015 or 6017 available from Ticona GmbH or "BD Crystal Clear Polymer" available from Zeon Chemicals of Japan and Topas® 8007 available from Ticona GmbH or Zeonor 750R available from Zeon Corporation. By adjusting the proportions of the blend of cyclic olefins or cyclic olefin copolymers, the desired melting temperature compatible with the inner layer of low density polyethylene can be achieved. Low density polyethylene including linear low density polyethylene and high pressure low density polyethylene are commercially available from numerous sources. Where the medical fluid delivery device of this invention includes a laminate comprised of three layers as shown in Figure 5, the first and second inner film layers 58 and 60 are coextruded with the outer film layer 54 and bonded during the coextrusion process. The delivery device 20 shown in Figure 5 may then be thermoformed as described above with reference to Figure 4, wherein the laminate is heated to its melting or thermoforming temperature and formed in a die by conventional thermoforming techniques.

The resultant medical fluid delivery devices 20 shown in Figures 4 and 5 have several important advantages over the known prior art, particularly including but not limited to the disclosure of U.S. Patent No. 4,955,871. First, because the laminate of this invention may be formed by coextrusion, wherein the melting temperatures of the lamina are very similar, the laminate is not subject to delamination and conventional coextrusion apparatus may be used. The manufacturing cost is also significantly reduced. Further, the clarity is improved. Finally, the laminate has improved safety, including very low extractables after radiation sterilization and toxic fumes are not generated during incineration or disposal. Finally, the laminate can be easily and permanently crushed during use, wherein the bulb-shaped liquid reservoir 22 is squeezed by the user, thereby preventing reuse.

As will be understood by those skilled in this art, various modifications may be made to the medical fluid delivery device of this invention within the purview of the appended claims. As set forth above, the medical fluid delivery device includes a collapsible crushable enclosure wall formed of a laminate as described above. However, the medical fluid delivery device of this invention is not limited to a syringe and the bulb-shaped enclosure may be of any suitable form provided the enclosure wall is collapsible and crushable to prevent reuse. For example only, the medical fluid delivery device of this invention may also be used as a respiratory delivery device.

CLAIMS

1. A medical fluid delivery device having a collapsible crushable enclosure wall formed of a laminate including an inner layer film of low density polyethylene bonded to an outer layer film of cyclic olefin of cyclic olefin copolymer having a melting temperature of between 1 to 10° C greater than the melting temperature of said inner layer film of low density polyethylene.

2. The medical fluid delivery device as defined in Claim 1, wherein said inner layer film of low density polyethylene has a thickness of between one and four mils.

3. The medical fluid delivery device as defined in Claim 1, wherein said outer layer film of cyclic olefin or cyclic olefin copolymer has a thickness of between one and seven mils.

4. The medical fluid delivery device as defined in Claim 1, wherein said inner and outer layer films are coextruded and then thermoformed.

5. The medical fluid delivery device as defined in Claim 1, wherein said collapsible crushable enclosure wall is sterilized by irradiation.

6. The medical fluid delivery device as defined in Claim 1, wherein said collapsible crushable enclosure wall is transparent.

7. The medical fluid delivery device as defined in Claim 1, wherein said inner layer film of low density polyethylene is comprised of two bonded film layers including a first film layer in contact with said medical fluid of linear low density polyethylene and a second layer bonded to said outer layer film of high pressure low density polyethylene.

8. The medical fluid delivery device as defined in Claim 7, wherein said first film layer has a thickness of between one and three mils and said second film layer has a thickness of between 0.5 and 2 mils.

9. The medical fluid delivery device as defined in Claim 1, wherein said outer layer film is a blend of at least two cyclic olefins or cyclic olefin copolymers having a blended melt temperature of between 1 to 10° C greater than said inner layer of low density polyethylene.

10. The medical liquid delivery device including a collapsible crushable enclosure formed of a transparent laminate comprising an inner layer film of low density polyethylene bonded to an outer layer film of a blend of at least two cyclic olefins or cyclic olefin copolymers having a blended melting temperature of 1 to 10° C greater than the melting temperature of said inner layer film of low density polyethylene.

11. The medical liquid delivery device as defined in Claim 10, wherein said inner layer film of low density polyethylene has a thickness of between 1 and 4 mils.

12. The medical liquid delivery device as defined in Claim 11, wherein said outer layer film of cyclic olefin or cyclic olefin copolymer has a thickness of between 1 and 7 mils.

13. The medical liquid delivery device as defined in Claim 10, wherein said inner and outer layer films are coextruded and then thermoformed.

14. The medical liquid delivery device as defined in Claim 13, wherein said collapsible crushable enclosure is thermoformed into a bulb-shape.

15. The medical liquid delivery device as defined in Claim 10, wherein said inner layer film of low density polyethylene comprises two bonded film layers including a first film layer in contact with said medical liquid of linear low density

polyethylene and a second film layer bonded to said outer layer film of high pressure low density polyethylene.

16. The medical liquid delivery device as defined in Claim 15, wherein said first film layer has a thickness of between 1 and 3 mils and said second film layer has a thickness of between 0.5 and 2 mils.

17. A medical liquid delivery device including a collapsible crushable enclosure formed of a transparent laminate including a first inner layer film of linear low density polyethylene, a second inner layer film bonded to said first inner layer film of high pressure low density polyethylene and an outer layer bonded to said second inner layer film of a cyclic olefin or cyclic olefin copolymer.

18. The medical liquid delivery device as defined in Claim 17, wherein said first and second inner layer films and said outer layer film are coextruded.

19. The medical liquid delivery device as defined in Claim 17, wherein the combined thickness of said first and second inner layer films is between 1 and 4 mils.

20. The medical liquid delivery device as defined in Claim 17, wherein said outer layer film has a thickness of between 1 and 7 mils.

21. The medical liquid delivery device as defined in Claim 17, wherein said outer layer film is a blend of at least two cyclic olefins or cyclic olefin copolymers having a blended melting temperature of between 1 to 10° C greater than said first inner layer film.

22. The medical liquid delivery device as defined in Claim 21, wherein said outer layer film has a melting temperature of at least 4° C greater than said first inner layer film.

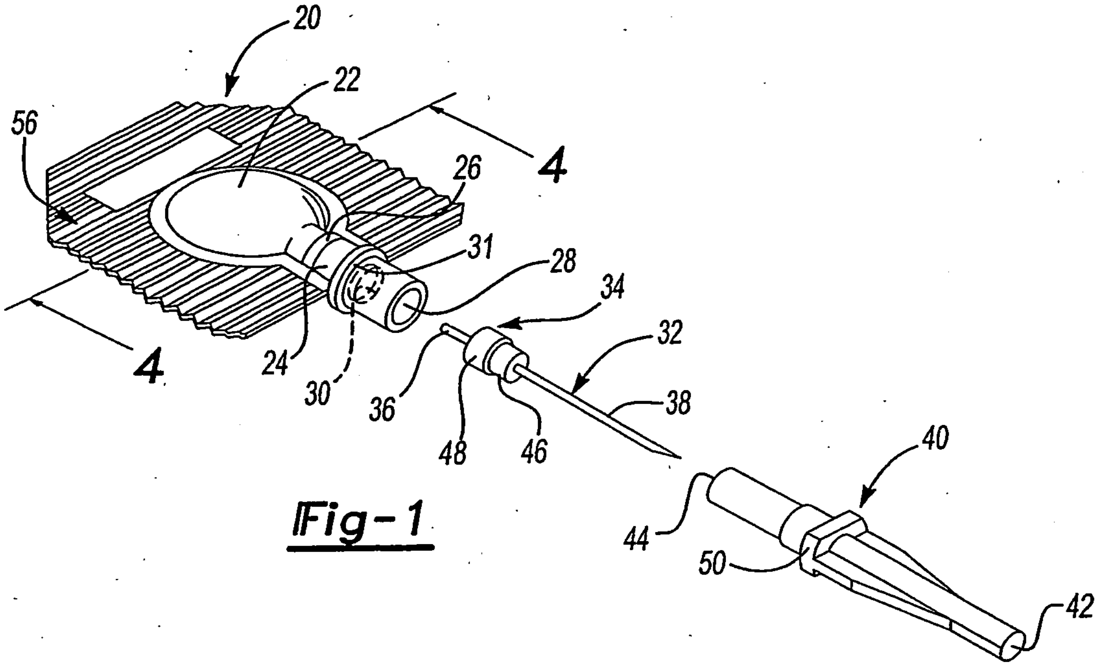
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Fig-1

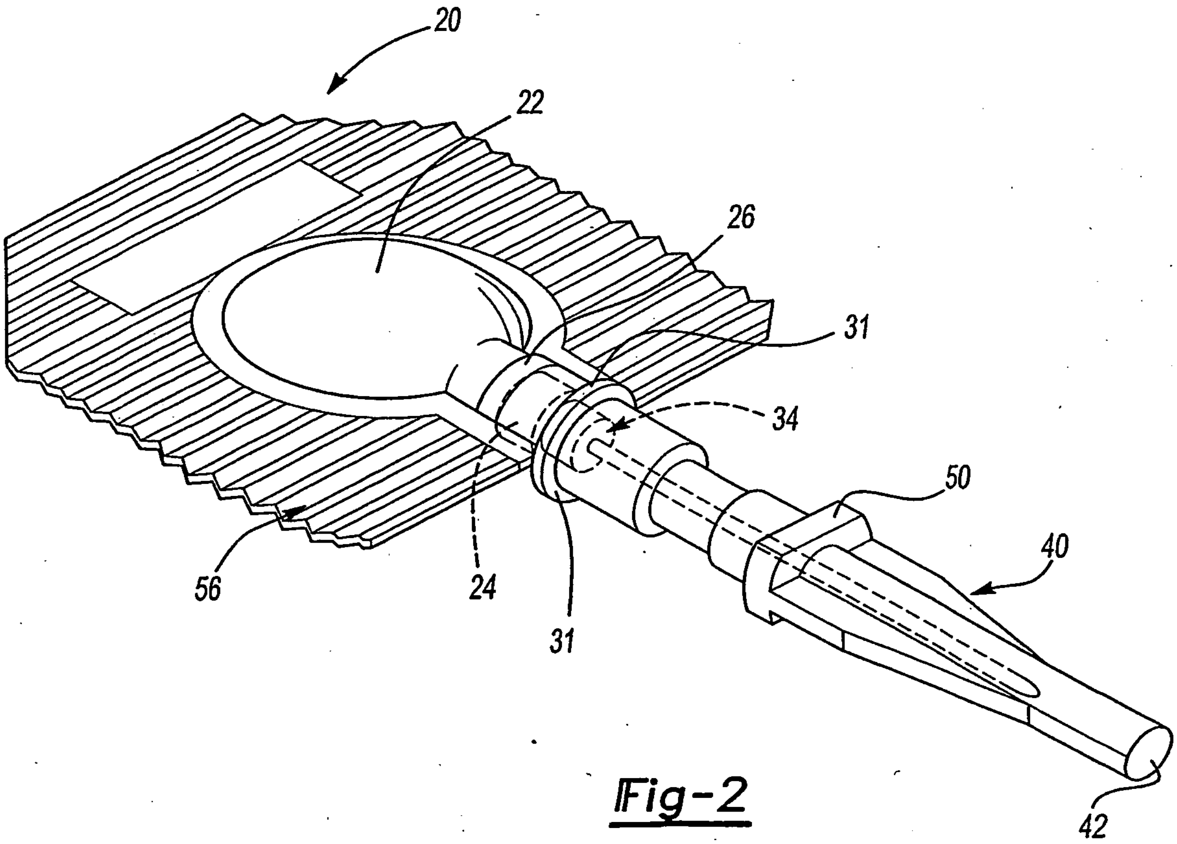
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Fig-2

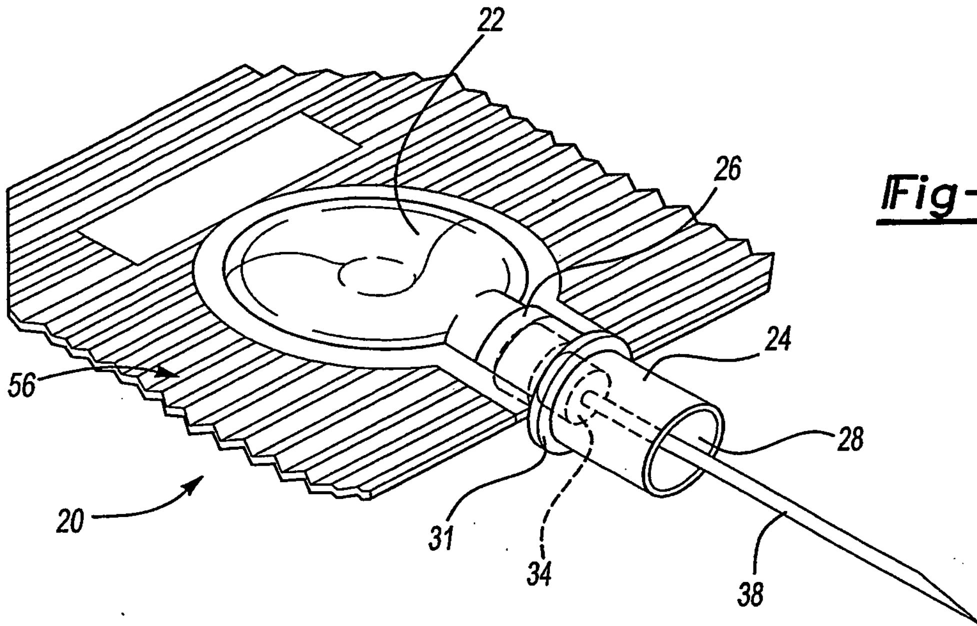

Fig-3

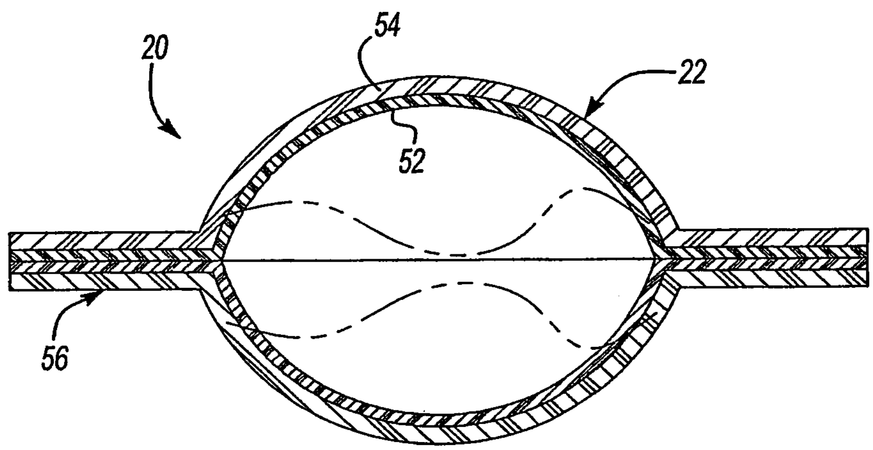

Fig-4

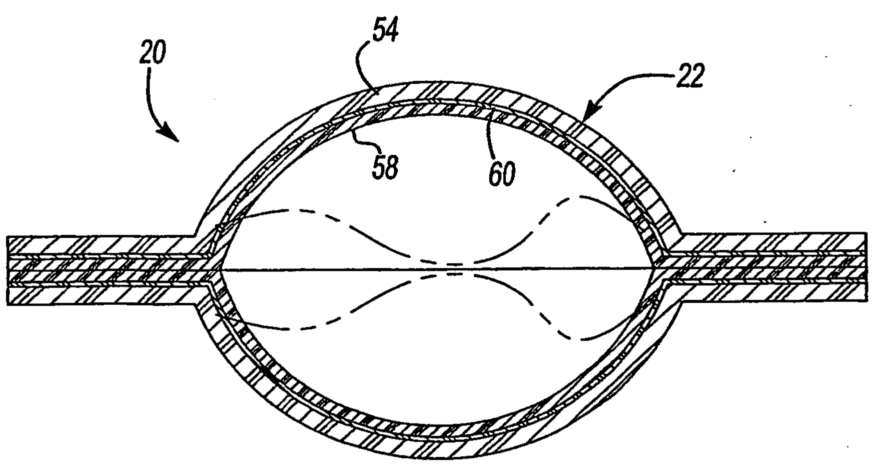

Fig-5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/29189

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 955 871 A (THOMAS RONNY D) 11 September 1990 (1990-09-11) cited in the application abstract	1-22
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☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 March 2003	12/03/2003

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European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nielsen, M

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